

REMARKS

Applicants re-submit their Amendment filed on June 25, 2004 to correct the Listing of Claims of the immediate application. According to the Notice of Non-Compliant Amendment mailed on October 18, 2004, the Listing of Claims filed by Applicants on June 25, 2004 included impermissible identifiers for claims 40-43. The Listing of Claims submitted herewith now includes proper identifiers for claims 40-43.

Claims 1-43 are pending in the present application. Claims 40-43 are allowed. Claim 39 is amended herein. Support for the amendments to claim 39 can be found in claim 39 as filed, in the paragraph bridging pages 36 and 37 of the specification and elsewhere throughout the specification. No new matter is believed to be added by these amendments. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

Rejection Under 35 U.S.C. § 102(b)

The Office Action states that claim 39 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Imaoka et al. (DNA Cell. Biol. 12 (10): 893-899 (1993)). According to the Office Action, Imaoka et al. disclose a method comprising detecting a mutant Cyp4A11 polypeptide or mutated Cyp4A11 nucleic acid in the subject.

As amended herein, claim 39 now recites “a method of identifying a subject having an increased susceptibility for developing hypertension, comprising: a) detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid in the subject, and; b) associating the mutant Cyp4A11 polypeptide or the mutated Cyp4A11 nucleic acid with an increased susceptibility for developing hypertension, thereby identifying a subject having an increased susceptibility for developing hypertension.

Imaoka et al. does not disclose any mutation associated with an increased susceptibility for developing hypertension, nor does it disclose any method for detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid in the subject, and associating the mutant Cyp4A11 polypeptide or the mutated Cyp4A11 nucleic acid with an increased susceptibility for developing hypertension. Since Imaoka et al. fails to

disclose each feature of the claimed invention, this reference does not anticipate the present invention. Thus, applicants respectfully request withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, first paragraph

The Office Action states that claim 39 is rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Further stated in the Office Action is that the claim allegedly contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

According to the Office Action, claim 39 is a genus claim in terms of a method of identifying a subject having an increased susceptibility for developing hypertension comprising detecting any mutant of Cyp4A11 polypeptide or nucleic acid which may be virtually any sequence. Further stated in the Office Action is that the disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the methods of detecting all encompassed polypeptide or nucleic acid variants of Cyp4A11 which would indicate increased susceptibility for developing hypertension. The Office Action also states that while the specification provides general information regarding the sequence of the Cyp4A11 polypeptide and nucleic acid sequence, there is no structure function analysis of said polypeptide or nucleic acid sequence to provide guidance on the regions which, when altered, would result in an increased susceptibility to hypertension. The Office Action further states that 4 individual amino acids out of the full-length polypeptide does not provide sufficient guidance on this matter. Therefore, the Office Action concludes that the specification does not describe the claimed method in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the method at the time of filing the present application.

As stated above, claim 39 is amended herein to recite “a method of identifying a subject having an increased susceptibility for developing hypertension, comprising: a) detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid in the

subject, and; b) associating the mutant Cyp4A11 polypeptide or the mutated Cyp4A11 nucleic acid with an increased susceptibility for developing hypertension, thereby identifying a subject having an increased susceptibility for developing hypertension.

Therefore, amended claim 39 is not directed to identifying a subject having an increased susceptibility for developing hypertension by identifying any mutant Cyp4A11 polypeptide or any mutated Cyp4A11 nucleic acid, but instead, amended claim 39 is directed to identifying a subject having an increased susceptibility for developing hypertension by identifying a mutant Cyp4A11 polypeptide or a mutated Cyp4A11 nucleic acid and associating the mutant Cyp4A11 polypeptide or mutated Cyp4A11 nucleic acid with an increased susceptibility for developing hypertension. In this regard, applicants respectfully remind the Examiner that claim 39 is a method directed to identifying Cyp4A11 mutation(s) that are associated with an increased susceptibility for developing hypertension. Thus, it is not necessary to know *a priori* which mutation(s) will be found in a particular Cyp4A11 polypeptide or nucleic acid sequence of a subject. Based on Applicants' discovery of Cyp4A11's role in hypertension and the association between mutant Cyp4A11 sequences (polypeptide and nucleic acid) and an increased susceptibility for hypertension, one of skill in the art would utilize the method as claimed to identify a mutation(s) in a Cyp4A11 polypeptide or Cyp4A11 nucleic acid of a subject and determine whether the mutation(s) is associated with an increased susceptibility for developing hypertension.

In response to the Examiner's assertion that one of skill in the art cannot envision all the methods of detecting all encompassed polypeptide or nucleic acid variants of Cyp4A11 which would indicate increased susceptibility for developing hypertension, Applicants respectfully point out that several methods of identifying mutations are provided on pages 37 and 38 of the specification. Furthermore, these methods and other methods of identifying mutations are considered routine. Therefore, one of skill in the art can readily perform numerous methods of identifying a mutant Cyp4A11 polypeptide or a mutant Cyp4A11 nucleic acid. In addition to performing routine methodology for the identification of a mutant in a Cyp4A11 polypeptide or a mutant Cyp4A11 nucleic acid, one of skill in the art can also perform a method comprising associating a mutant Cyp4A11 sequence with an increased susceptibility for developing hypertension. As

stated by Applicants on page 36, lines 18-21, “[b]y ‘increased susceptibility for developing hypertension’ is meant a subject who has a greater than normal chance of developing hypertension, compared to the general population. Such subjects include, for example, a subject that harbors a mutation in a Cyp4A11 gene such that biological activity of Cyp4A11 is altered.” Therefore, based on the teachings of the present invention, one of skill in the art can identify a mutant Cyp4A11 sequence and readily assess whether a mutation in a Cyp4A11 sequence results in altered biological activity. For example, one of skill in the art can assess the effects of a mutated Cyp4A11 on a subject’s blood pressure. Furthermore, it is also routine for one of skill in the art to utilize statistical analysis to determine if a mutant Cyp4A11 in a subject results in a greater than normal chance of developing hypertension, as compared to the general population.

As stated above, the Office Action alleges that although the specification provides general information regarding the sequence of the Cyp4A11 polypeptide and nucleic acid sequence, there is no structure function analysis of said polypeptide or nucleic acid sequence to provide guidance on the regions which, when altered, would result in an increased susceptibility to hypertension.

In response, Applicants respectfully remind the Examiner that sequences used in a claimed method need not have this type of written description because only the “invention” need be described, *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116-18 (Fed. Cir. 1991), and a method is an invention made up of process steps. Only the steps need be described, and the sequences used in a method need only be described so as to enable their use because only the enablement make and use requirement of 35 U.S.C. § 112, first paragraph, is implicated. Thus, it is not necessary for Applicants to describe which mutant Cyp4A11 sequences would result in an increased susceptibility to hypertension because the steps of the method are adequately described such that one of skill in the art can readily envision identifying a mutant Cyp4A11 sequence and associating it with an increased susceptibility for developing hypertension.

Thus, Applicants believe that the method of claim 39 does not include a scope that the skilled person would view as outside of applicants’ possession when the

application was filed. Therefore, it would be clear to one of skill in the art that applicants were in possession of the invention as claimed. Thus, applicants believe this rejection has been overcome and respectfully request its withdrawal.

No additional fee is believed due. However, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,
NEEDLE & ROSENBERG, P.C.

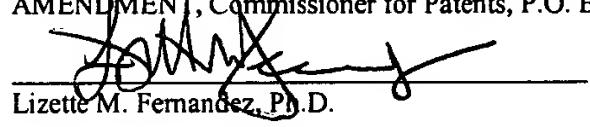


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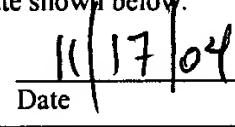
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I hereby certify that this AMENDMENT, and any item indicated as being attached or included, is being sent via first class mail to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.



Lizette M. Fernandez, P.D.


Date